

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS

PUBLIC HEALTH AND MEDICAL
PROFESSIONALS FOR TRANSPARENCY,

and

PATRICK AND STEPHANIE DE GARAY,

Plaintiffs,

-against-

FOOD AND DRUG ADMINISTRATION,

Defendant.

Civil Action No. 4:22-cv-915

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiffs, as for their Complaint regarding Freedom of Information Act requests against the above-captioned Defendant, allege as follows:

INTRODUCTION

1. On January 31, 2022, the Food and Drug Administration (“**FDA**”) approved the Moderna COVID-19 Vaccine, marketed as Spikevax (the “**Moderna Vaccine**”) for individuals 18 years of age and older.¹

2. On July 8, 2022, FDA approved the Pfizer-BioNTech COVID-19 Vaccine, marketed as Comirnaty, for individuals 12 through 15 years of age (the “**12-15-Year-Old Pfizer Vaccine**”).²

¹<https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-key-action-approving-second-covid-19-vaccine>.

² <https://www.fda.gov/news-events/press-announcements/fda-roundup-july-8-2022>.

3. For the Moderna Vaccine, FDA asserts that “Spikevax meets the FDA’s high standard for safety, effectiveness, and manufacturing quality required of any vaccine approved for use in the United States.”³

4. Similarly, for the 12-15-Year-Old Pfizer Vaccine, FDA asserts its “approval follows a rigorous analysis and evaluation of the safety and effectiveness data conducted by FDA.”⁴

5. Despite FDA’s assertions, numerous public health officials, media outlets, journalists, scientists, politicians, public figures, and others with large social or media platforms have publicly raised questions regarding the sufficiency of the data and information, the adequacy of the review, and the appropriateness of the analyses relied upon by FDA to license the Moderna Vaccine and the 12-15-Year-Old Pfizer Vaccine (the “**COVID-19 Vaccines**”).

6. Plaintiff Public Health and Medical Professionals for Transparency (“**PHMPT**”) is an organization made up of public health professionals, medical professionals, scientists, and journalists. PHMPT exists for the sole purpose of disseminating to the public the data and information in the biological product files of each of the COVID-19 vaccines.

7. In furtherance of its mission, and in an effort to ensure that FDA acts in furtherance of its commitment to transparency,⁵ PHMPT previously sought to obtain the data and information relied upon to license Comirnaty, Pfizer’s COVID-19 vaccine for individuals 16 years of age and older. As a result of an Order from this Court, FDA is currently producing that data which PHMPT makes available to the public as it is produced.

³<https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-key-action-approving-second-covid-19-vaccine>.

⁴ <https://www.fda.gov/news-events/press-announcements/fda-roundup-july-8-2022>.

⁵ <https://www.fda.gov/about-fda/transparency>.

8. PHMPT now seeks to obtain additional data and information relied upon by FDA to license the COVID-19 Vaccines. The importance of releasing this information to the public is also recognized under federal regulation which provides: “After a license has been issued, the following data and information in the biological product file are immediately available for public disclosure unless extraordinary circumstances are shown: (1) All safety and effectiveness data and information. (2) A protocol for a test or study” 21 C.F.R. § 601.51(e).

9. Upon licensure for each of the COVID-19 Vaccines, PHMPT therefore issued two requests to FDA pursuant to the Freedom of Information Act (5 U.S.C. § 552, as amended) (“FOIA”) for “[a]ll data and information for [the COVID-19 Vaccines] enumerated in 21 C.F.R. § 601.51(e)^[6] with the exception of publicly available reports on the Vaccine Adverse Events Reporting System.”⁷

10. A near identical request for the 12-15-Year-Old Pfizer Vaccine was later submitted to FDA by Patrick and Stephanie de Garay (the “**de Garays**”), parents of minor M.D., who suffered substantial injuries from a serious and ongoing adverse reaction to the 12-15-Year-Old Pfizer Vaccine during her participation in Pfizer’s clinical trial for 12- to 15-year-olds.⁸

11. The public and the medical and scientific community have a substantial interest in reviewing the data and information underlying FDA’s approval of the COVID-19 Vaccines.

⁶ 21 C.F.R. § 601.51(e) provides that, after a biological product is licensed, the following information shall be made available for immediate disclosure absent extraordinary circumstances: “(1) All safety and effectiveness data and information. (2) A protocol for a test or study (3) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information (4) A list of all active ingredients and any inactive ingredients (5) An assay method or other analytical method (6) All correspondence and written summaries of oral discussions relating to the biological product file (7) All records showing the manufacturer’s testing of a particular lot (8) All records showing the testing of and action on a particular lot by the [FDA].”

⁷ For the avoidance of doubt, the FOIA Request includes, but is not limited to, all of the data and information in the biological product file, as defined in 21 C.F.R. § 601.51(a), for [the COVID-19 Vaccines], enumerated in 21 C.F.R. § 601.51(e), with the exception of publicly available reports on the Vaccine Adverse Events Reporting System.

⁸ <https://www.foxnews.com/media/ohio-woman-daughter-covid-vaccine-reaction-wheelchair>; *see also* <https://thehighwire.com/videos/rigged-maddies-story/>.

12. Releasing this data should also confirm FDA's conclusion that the COVID-19 Vaccines are safe and effective and, thus, further the FDA's mission to increase confidence in the COVID-19 Vaccines and their uptake.

13. The public's need for this information is urgent given the fact that the COVID-19 Vaccines have been, or continue to be, mandated for large segments of the American public. Moreover, both public and private policy makers continue to adjust their vaccine policies based on the information that is publicly available and publicized by influential participants on both sides of the ongoing public debate regarding the COVID-19 Vaccines' safety and effectiveness.

14. With legislators, policy makers, and parents deciding how best to protect Americans of all ages during the upcoming winter season and academic school year, there is no more urgent or appropriate time for the immediate disclosure of the COVID-19 Vaccines' biological product files ("**BLA files**"). The public's value in the release of the BLA files would be significantly diminished if the disclosure were delayed because millions of Americans, and their policy makers, will be making these medical and policy decisions in the coming months. If the disclosure of the BLA files is delayed, many of these Americans, and many on behalf of their children, will be forced to make irreversible medical decisions before the independent scientific community and journalists have had time to review and report upon the basis for FDA's licensure of the COVID-19 Vaccines.

15. In an effort to disseminate the requested information to the public as expeditiously as possible, given the time sensitive nature of the issue, both PHMPT and the de Garays (collectively, the "**Plaintiffs**") requested expedited processing of the FOIA requests pursuant to 5 U.S.C. § 552(a)(6)(E)(v)(II).

16. On March 7, 2022, FDA denied PHMPT's request for expedited processing of its FOIA request regarding the Moderna Vaccine. PHMPT appealed the decision on June 1, 2022 and FDA still has not resolved that appeal.

17. On August 15, 2022, FDA denied PHMPT's request for expedited processing for its FOIA request regarding the 12-15-Year-Old Pfizer Vaccine.

18. Similarly, on August 29, 2022, FDA denied the de Garays' request for expedited processing of their FOIA request regarding the 12-15-Year-Old Pfizer Vaccine.

19. The Plaintiffs bring this action to challenge FDA's determinations and to seek an order compelling FDA to produce responsive records on an expedited basis.

PARTIES

20. Public Health and Medical Professionals for Transparency is a not-for-profit organization with an office located at 1090 Texan Trail, Suite 534, Grapevine, Texas, 76051 in Tarrant County, Texas.

21. To date, PHMPT has approximately 5,865 members, including medical and public health professionals, such as professors and researchers in medical-related disciplines from Yale School of Public Health, UCLA David Geffen School of Medicine, University of Maryland School of Pharmacy, The Warren Alpert Medical School of Brown University, Oregon Health & Science University, University of California San Francisco, David Geffen School of Medicine at UCLA, University of Leicester, University of Southern Denmark, The University of Sydney, University of Oxford, Institute for Scientific Freedom, University of Toronto, University of Auckland, University of Muenster, and Deutenomics Science Institute, as well as other universities and journalists.

22. Patrick and Stephanie de Garay reside in Clermont County, Ohio and are the parents of 14-year-old M.D., who has suffered and continues to suffer severe adverse events following vaccination in Pfizer’s clinical trial for 12- to 15-year-olds.

23. FDA is an agency within the Executive Branch of the United States Government, organized within the Department of Health and Human Services. FDA is an agency within the meaning of 5 U.S.C. § 552(f).

JURISDICTION AND VENUE

24. This Court has jurisdiction over this action pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1331. Venue is proper within this District pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1391.

FACTS

I. FDA Licensure of COVID-19 Vaccines

25. FDA may only license vaccines that have been proven to be “safe and effective,” *see, e.g.*, 21 U.S.C. § 393, and FDA makes this determination based on, *inter alia*, clinical trial reports provided by the sponsor which must be sufficient to demonstrate the product is both “safe” and “effective.”⁹ 21 C.F.R. 601.2(a).

26. In order to demonstrate that they are safe and effective, Pfizer and Moderna conducted clinical trials for each of their COVID-19 vaccines and reported results of those trials, as well as other studies, to the FDA as part of their products’ BLA files.

⁹ FDA explains in its guidance materials that the clinical trials relied upon for approval are typically “1 to 4 years” (<https://www.fda.gov/patients/drug-development-process/step-3-clinical-research>) and the duration of clinical trials should “reflect the product and target condition.” <https://www.fda.gov/media/102332/download>; *see also* <https://www.fda.gov/consumers/consumer-updates/it-really-fda-approved>; <https://www.fda.gov/about-fda/what-we-do>.

A. FDA Licensure of Pfizer's Comirnaty Vaccine and PHMPT's Related Case

27. Upon licensure of Pfizer's first COVID-19 vaccine, Comirnaty, for use in individuals 18 years and older, PHMPT submitted a FOIA request to obtain the data within the product's BLA file. Like in the instant action, PHMPT's expedited processing request was denied and PHMPT commenced a litigation, *Public Health and Medical Professionals for Transparency v. Food and Drug Administration*, 4:21-cv-01058-P, in this Court to obtain the documents from FDA.

28. On January 6, 2022, this Court ordered FDA to produce the responsive documents from Comirnaty's BLA file at a rate of 55,000 pages every 30 days until production is complete. The parties subsequently agreed to, and the Court ordered, slight modifications of the production schedule; however, the parties maintained the rate of 55,000 pages every 30 days for a majority of the production. That BLA file is currently being produced and, to date, has resulted in approximately 470,614 pages of documents being made public.

29. The public has shown great interest in these documents. To date, and as explained further below, there have been approximately three-quarters of a million downloads of the documents and data released and PHMPT's website itself has drawn over 2.7 million visitors and 4.5 million views in the last 12 months.

30. Once the entirety of the BLA file has been produced, independent experts and researchers will be able to conduct their own analyses about the efficacy of the vaccine.

B. FDA's Licensure of Pfizer's 12-15-Year-Old Vaccine and Moderna's Vaccine

31. Following the start of the clinical trials for Pfizer's vaccine for persons 16 years of age and older, Pfizer conducted clinical trials in children ages 12 to 15 years old.

32. The Plaintiffs' daughter, M.D., was one of the participants in Pfizer's clinical trials for the 12-15-Year-Old Pfizer Vaccine.¹⁰ In fact, she was one of only approximately 1,000 children in this age range who were injected with the investigational vaccine. Within 24-hours of receiving the second dose of the vaccine during the clinical trial, M.D. experienced a serious adverse reaction to the vaccine, including severe pain throughout her body and the feeling that her "heart was being ripped out through her neck," and she presented to the emergency room.¹¹ M.D. was subsequently admitted to the hospital and later discharged with the diagnosis that her symptoms were the result of adverse reaction to the vaccine.¹² M.D.'s health continued to rapidly decline and, despite the de Garays' thorough documentation, reporting, and outreach regarding their daughter's sudden onset symptoms – which ultimately necessitated her continued use of a feeding tube and wheelchair – the de Garays received no attention from Pfizer or the FDA.¹³ In Pfizer's data presented to the FDA in its application for an EUA, M.D.'s severe, systemic, and ongoing adverse reaction to the 12-15-Year-Old Pfizer Vaccine was categorized as "functional abdominal pain."¹⁴

33. Notwithstanding the de Garays' reporting of their daughter's wide range of severe symptoms, Pfizer's inaccurate and misleading characterization thereof, and the safety alarms that this should have been ringing, FDA granted the vaccine EUA and subsequently licensed the use of the 12-15-Year-Old Pfizer Vaccine on July 8, 2022.¹⁵

¹⁰ See Patrick de Garay's Declaration (**Exhibit 7** at pages 9-10.)

¹¹ <https://thehighwire.com/videos/rigged-maddies-story/> (see video at 6:44-8:20)

¹² *Id.*

¹³ See generally *id.*

¹⁴ *Id.* at 1:04:40

¹⁵ See <https://www.fda.gov/news-events/press-announcements/fda-roundup-july-8-2022>.

34. The Moderna Vaccine was likewise licensed by the FDA on January 31, 2022.¹⁶

35. The Code of Federal Regulations expressly provides that “[a]fter a license has been issued, the following data and information in the biological product file are *immediately available for public disclosure* unless extraordinary circumstances are shown: (1) All safety and effectiveness data and information . . .” 21 C.F.R. § 601.51(e) (emphasis added).

36. There is an ongoing, national public debate regarding the adequacy of the data and information, and analyses of same, relied upon by FDA to license the COVID-19 Vaccines.

37. On the one hand, there are numerous public health officials, media outlets, journalists, scientists, politicians, public figures, and others with large social or media platforms that have declared that the data and information underlying the licensure of the Moderna Vaccine is more than sufficient for licensure.

38. For example, in a press release issued on January 31, 2022, then-acting FDA Commissioner Janet Woodcock stated,

The public can be assured that Spikevax [the Moderna Vaccine] meets the FDA’s high standards for safety, effectiveness, and manufacturing quality required of any vaccine approved for use in the United States. While hundreds of millions of doses of Moderna COVID-19 Vaccine have been administered to individuals under emergency use authorization, we understand that for some individuals, FDA approval of this vaccine may instill additional confidence in making the decision to get vaccinated.¹⁷

Peter Marks, MD, PhD, the Director of FDA’s Center for Biologics Evaluation and Research, made similar remarks:

¹⁶ <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-key-action-approving-second-covid-19-vaccine>.

¹⁷ <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-key-action-approving-second-covid-19-vaccine>.

The FDA’s medical and scientific experts conducted a thorough evaluation of the scientific data and information included in the application pertaining to the safety, effectiveness, and manufacturing quality of Spikevax [the Moderna Vaccine]. This includes the agency’s independent verification of analyses submitted by the company, our own analyses of the data, along with a detailed assessment of the manufacturing processes, test methods and manufacturing facilities. Safe and effective vaccines are our best defense against the COVID-19 pandemic, including currently circulating variants. The public can be assured that this vaccine was approved in keeping with the FDA’s rigorous scientific standards.¹⁸

39. Even prior to FDA’s approval of the Moderna Vaccine, government officials, public health authorities, and medical professionals repeatedly claimed that COVID-19 vaccines were “safe and effective.”¹⁹

40. For the 12-15-Year-Old Pfizer Vaccine, FDA asserts that its approval followed “a rigorous analysis and evaluation of the safety and effectiveness data conducted by FDA”²⁰ and the Center for Disease Control and Prevention (“CDC”) currently “recommends COVID-19 vaccines for everyone 6 months and older and boosters for everyone 5 years and older.” Furthermore, CDC states generally²¹ that

COVID-19 vaccines have undergone – and will continue to undergo – the most intensive safety monitoring in the U.S. history. Evidence from hundreds of millions of COVID-19 vaccines already administered in the United States, and billions of vaccines administered globally, demonstrate that they are safe and effective.

¹⁸ *Id.*

¹⁹ See, e.g., <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html>; see also <https://www.who.int/news-room/feature-stories/detail/vaccine-efficacy-effectiveness-and-protection> (“COVID-19 vaccines have proven to be safe, effective and life-saving.”); <https://www.doh.wa.gov/Emergencies/COVID19/Vaccine-Information/Safety-and-Effectiveness> (“COVID-19 vaccines are safe.”).

²⁰ <https://www.fda.gov/news-events/press-announcements/fda-roundup-july-8-2022>.

²¹ <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/Pfizer-BioNTech.html>.

41. On the other hand, numerous public health officials, media outlets, journalists, scientists, politicians, public figures, and others with large social or media platforms have publicly raised questions regarding the sufficiency of the data and information, the adequacy of the review, and the appropriateness of the analyses relied upon to the license the COVID-19 Vaccines, including a number of scientists and journalists who are members of PHMPT.

42. For example, on June 1, 2021, a group of 27 clinicians, scientists, and patient advocates, including PHMPT members Peter Doshi, PhD, Senior Editor for The BMJ and Associate Professor of Pharmaceutical Health Services Research at the University of Maryland School of Pharmacy,²² and Peter A. McCullough, MD, former Professor of Medicine at Texas A&M College of Medicine, filed a Citizen Petition²³ with FDA, stating that the available evidence for licensure of the COVID-19 Vaccines “is simply not mature enough at this point to adequately judge whether clinical benefits outweigh the risks in all populations.”²⁴ Separately, Dr. Doshi has publicly questioned the lack of transparency regarding the vaccine approval process²⁵ which Peter Marks, MD, PhD, Director of FDA’s Center for Biologics Evaluation and Research, publicly disputed.²⁶

43. More recently, a paper published on June 23, 2022 and updated on September 9, 2022 titled, *Serious Adverse Events of Special Interest Following mRNA Vaccination in Randomized Trials*, states: “These study limitations all stem from the fact that the raw data from

²² <https://www.bmj.com/about-bmj/editorial-staff/peter-doshi>.

²³ <https://www.regulations.gov/document/FDA-2021-P-0521-0001>.

²⁴ See <https://blogs.bmj.com/bmj/2021/06/08/why-we-petitioned-the-fda-to-refrain-from-fully-approving-any-covid-19-vaccine-this-year/>.

²⁵ See <https://blogs.bmj.com/bmj/2021/08/23/does-the-fda-think-these-data-justify-the-first-full-approval-of-a-covid-19-vaccine/>; <https://blogs.bmj.com/bmj/2021/01/04/peter-doshi-pfizer-and-modernas-95-effective-vaccines-we-need-more-details-and-the-raw-data/>; <https://blogs.bmj.com/bmj/2020/11/26/peter-doshi-pfizer-and-modernas-95-effective-vaccines-lets-be-cautious-and-first-see-the-full-data/>.

²⁶ <https://www.statnews.com/2020/12/17/did-the-fda-understaff-its-review-of-the-pfizer-biontech-vaccine/>.

COVID-19 vaccine clinical trials are not publicly available. Given the global public health implications, **there is an urgency to make all COVID-19 trial data public, particularly regarding serious adverse events, without any further delay.**”²⁷

44. Numerous other recent papers have presented data that have called into serious question the efficacy of these vaccines, including data that reflect issues which should have been seen during the clinical trial if it had been conducted properly and the results fully reported to the FDA:

- a. An article in the New England Journal of Medicine discusses a study that included 887,193 children (273,157 vaccinated children) and showed that children who had COVID-19 and were subsequently vaccinated were much more likely to get reinfected than their peers who also had COVID-19 and were not vaccinated.²⁸
- b. Data from the Dutch government evaluating mRNA vaccines found that “in the period from March 15 to June 28, 2022, there was hardly any visible protective effect of the COVID-19 basic vaccination series against hospital and ICU-intake.” In fact, when researchers stratified the risks of hospitalization and intensive care by time from the date of vaccination and by age, it was demonstrated that the risks increase over time.²⁹
- c. A study among adolescents in Brazil and Scotland analyzed vaccine effectiveness of two doses of Pfizer’s vaccine against symptomatic and severe COVID-19. The

²⁷ Fraiman, J., et al., *Serious adverse events of special interest following mRNA vaccination in randomized trials*, SSRN (June 23, 2022) https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4125239 (emphasis added).

²⁸ See Lin, Dan-yu, et al., *Letter to the Editor: Effects of Vaccination and Previous Infection on Omicron Infections in Children*, NEJM (Sept. 22, 2022) https://www.nejm.org/doi/full/10.1056/NEJMc2209371?query=featured_home.

²⁹ See <https://www.rivm.nl/covid-19-vaccinatie/bescherming-coronavaccins-tegen-ziekenhuisopname/booster-en-herhaalprik-bij-ouderen-nodig-om-bescherming-op-peil-te-brengen> (Dutch version). <https://www.rivm.nl/en/covid-19-vaccination/vaccine-effectiveness-in-preventing-hospital-admissions/covid-19-booster-jab-and-repeat-vaccination-needed-for-older-people-to-restore-protection> (English version).

study found waning vaccine protection against symptomatic COVID-19 from 27 days after the second dose.³⁰

- d. A study published in the *Lancet* looking at effectiveness of Pfizer's vaccine in children in Italy states: "Our estimates of the effectiveness of full vaccination against SARS-CoV-2 infection are significantly lower than those reported in the clinical trial that led to the approval of BNT162b2 in children (90.7% in the approval trial vs 29.4% in our study)." The study also states, "our estimates of vaccine effectiveness against infection coincide with the estimate reported in the USA in a previous study" and that "this decline could be due to immunity waning, as described in the adult population vaccinated with mRNA vaccines."³¹
- e. A study printed in *JAMA*, which was conducted from December 2021 to February 2022 during Omicron variant predominance and included 121,952 tests from sites across the United States, estimated vaccine effectiveness against symptomatic infection among adolescents 12 to 15 years of age at 16.6% at two months after two doses. The study concluded: "Among children and adolescents, estimated VE for 2 doses of [Pfizer's vaccine] was modest and decreased rapidly."³²

45. Likewise, numerous recent papers have presented data of serious safety issues with these vaccines, including data that reflect issues which should have been seen during the clinical

³⁰ See Florentino, P.T. *et al.*, *Vaccine effectiveness of two-dose BNT162b2 against symptomatic and severe COVID-19 among adolescents in Brazil and Scotland over time: a test-negative case-control study*, *Lancet Infect Dis.* (Aug. 8, 2022) <https://pubmed.ncbi.nlm.nih.gov/35952702/>.

³¹ See Sacco, C., *et al.*, *Effectiveness of BNT162b2 vaccine against SARS-CoV-2 infection and severe COVID-19 in children aged 5-11 years in Italy: a retrospective analysis of January-April, 2022*, *The Lancet* (July 9, 2022) [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(22\)01185-0/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(22)01185-0/fulltext).

³² See Fleming-Dutra, K., *et al.*, *Association of Prior BNT162b2 COVID-19 Vaccination With Symptomatic SARS-CoV-2 Infection in Children and Adolescents During Omicron Predominance*, *AMA JAMA* (June 14, 2022) <https://pubmed.ncbi.nlm.nih.gov/35560036/>.

trial if it had been conducted properly and the results fully reported to the FDA, including immune, neurological and circulatory system disorders. For example, the following is a list of studies on the adverse effects on the heart and circulatory system in children from the COVID-19 vaccine:

- a. A recent study in the American Heart Association journal, conducted between December 2020 and December 2021, acknowledged that deaths had resulted from myocarditis post-vaccination, identifying 345 people in England who had died of myocarditis after receiving a COVID-19 vaccine.³³
- b. Another study in Tropical Medicine and Infectious Disease of 301 adolescents found that 54 patients, or 17.94%, had abnormal electrocardiograms after vaccination with Pfizer's COVID-19 vaccine, resulting in one case of myopericarditis, four cases of subclinical myocarditis, and two cases of pericarditis.³⁴
- c. A Kaiser Permanente study determined that the rate of myocarditis used by federal health authorities was incorrect and that the actual rate was nearly double, at 1 in 4,800 children vaccinated, observing, "The true incidence of myopericarditis is markedly higher than the incidence reported to US advisory committees," as the study had identified "approximately twice as many cases of myopericarditis following COVID-19 mRNA vaccination."³⁵

³³ Patone, M., *et al.*, *Risk of Myocarditis After Sequential Doses of COVID-19 Vaccine and SARS-CoV-2 Infection by Age and Sex*, *Circulation* (Aug. 22, 2022), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9439633/>.

³⁴ Mansanguan, S., *et al.*, *Cardiovascular Manifestation of the BNT162b2 mRNA COVID-19 Vaccine in Adolescents*, *Tropical Med. & Infec. Dis.* (Aug. 19, 2022), <https://www.mdpi.com/2414-6366/7/8/196/htm>.

³⁵ Shariff, K., *et al.*, *Risk of Myopericarditis following COVID-19 mRNA vaccination in a Large Integrated Health System: A Comparison of Completeness and Timeliness of Two Methods*, *MedRxiv* (Dec. 27, 2021), <https://www.medrxiv.org/content/10.1101/2021.12.21.21268209v1.full.pdf>.

- d. A study from the Norwegian Institute of Public Health involving 23.1 million Scandinavians ages 12 and up found that the risk of myocarditis after mRNA vaccines was highest in males aged 16 to 24 after the second dose.³⁶
- e. An analysis of 42 million people ages 13 and older by Oxford researchers found higher rates of vaccine-induced myocarditis than COVID-19-induced myocarditis in males ages 16 to 39 after second and third doses of Pfizer's COVID-19 vaccine and after first and second doses of Moderna's COVID-19 vaccine.³⁷

II. Vaccine Mandates

46. The public debate over the safety and effectiveness of the COVID-19 Vaccines concerns matters of current exigency to the American public because it has also led to invasive policy decisions that affect the livelihoods of the American public. Over the objections of many, Americans are still being mandated or otherwise pressured to take this product by the federal

³⁶ Karlstad, O., *et al.*, *SARS-CoV-2 Vaccination and Myocarditis in a Nordic Cohort Study of 23 Million Residents*, JAMA Cardiology (Apr. 20, 2022), <https://jamanetwork.com/journals/jamacardiology/fullarticle/2791253>.

³⁷ Patone, M., *et al.*, *Risk of Myocarditis Following Sequential COVID-19 Vaccinations by Age and Sex*, MedRxiv (Dec; 25, 2021), <https://www.medrxiv.org/content/10.1101/2021.12.23.21268276v1.full.pdf+html>.

government,³⁸ local governments,³⁹ public and private employers,⁴⁰ universities,⁴¹ schools,⁴² and various other institutions.⁴³

47. Furthermore, now that FDA has approved the 12-15-Year-Old Pfizer Vaccine, there are many indications that states and school districts will begin mandating these vaccines for

³⁸ See, e.g., <https://www.natlawreview.com/article/covid-19-vaccine-added-to-requirements-green-card-processing-effective-oct-1>; <https://apnews.com/article/business-health-coronavirus-pandemic-coronavirus-vaccine-4cf7451267919302de4a7b591508e80c>; <https://media.defense.gov/2021/Aug/25/2002838826/-1/-1/0/MEMORANDUM-FOR-MANDATORY-CORONAVIRUS-DISEASE-2019-VACCINATION-OF-DEPARTMENT-OF-DEFENSE-SERVICE-MEMBERS.PDF>.

³⁹ See, e.g., <https://www.cnn.com/2021/08/12/us/san-francisco-vaccine-requirement/index.html>; <https://www1.nyc.gov/site/doh/covid/covid-19-vaccines-keytonyc.page>; <https://news.yahoo.com/orleans-now-requires-proof-vaccination-230433492.html?guccounter=1>.

⁴⁰ See, e.g., <https://www.cnbc.com/2021/08/06/united-airlines-vaccine-mandate-employees.html>; <https://sanfrancisco.cbslocal.com/2021/08/02/covid-kaiser-permanente-makes-vaccination-mandatory-for-all-employees/>; <https://abcnews.go.com/Health/wireStory/walmart-mandates-vaccines-workers-headquarters-79177220>; <https://www.kpbs.org/news/2021/aug/17/encinitas-covid-19-vaccine-negative-test-employees/>; <https://www.cnbc.com/2021/08/09/covid-vaccine-mandates-sweep-across-corporate-america-as-delta-surges.html>; <https://www.reuters.com/business/energy/chevron-begins-covid-19-vaccination-mandates-wsj-2021-08-23/>; <https://thehill.com/policy/healthcare/569051-pfizers-full-approval-triggers-new-vaccine-mandates/>; <https://www.cvshealth.com/news-and-insights/statements/cvs-health-will-require-covid-19-vaccinations-for-clinical-and-corporate-employees>.

⁴¹ See e.g., <https://blockclubchicago.org/2022/07/18/will-your-college-still-require-covid-vaccinations-now-that-the-state-dropped-its-mandate/>; <https://www.nbcnews.com/health/health-news/colleges-universities-covid-vaccination-mandates-facing-pushback-n1273916>; <https://www.colorado.edu/covid-19/updates/covid-19-vaccination>; <https://uhs.berkeley.edu/requirements/covid19>.

⁴² See, e.g., <https://abcnews.go.com/US/dc-require-students-12-older-vaccinated-covid-19/story?id=87130087>; <https://www.4j.lane.edu/coronavirus/healthsafety/> (school staff and volunteers must get COVID-19 vaccine); <https://www.npr.org/sections/back-to-school-live-updates/2021/08/20/1029837338/a-california-school-district-mandates-vaccines-for-eligible-students>; <https://patch.com/massachusetts/salem/salem-school-committee-approves-vaccine-mandate-sports-band>; <https://www.nbcnewyork.com/news/coronavirus/nyc-will-require-vaccination-for-high-risk-school-sports/3232745/>; <https://www.nj.com/hudson/2021/08/hoboken-believed-to-be-first-in-state-to-issue-mandate-for-students-12-and-up-get-vaccine-or-face-weekly-testing.html>; <https://www.mercurynews.com/2021/08/19/la-county-school-district-mandates-covid-vaccines-for-k12-kids-others-soon-may-follow/>.

⁴³ See, e.g., <https://www.reuters.com/world/us/new-york-city-mandates-covid-19-vaccine-public-school-teachers-staff-mayor-2021-08-23/>; <https://www.cbsnews.com/news/california-covid-vaccine-teachers-mandate/>; <https://www.nytimes.com/2021/08/18/us/washington-state-teacher-vaccine-mandate.html>; <https://www.governor.ny.gov/news/governor-cuomo-announces-covid-19-vaccination-mandate-healthcare-workers>; <https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/FAQ-Health-Care-Worker-Vaccine-Requirement.aspx>; <https://www.nytimes.com/2021/08/09/us/washington-state-workers-vaccine-mandate.html>; <https://www.denvergov.org/Government/COVID-19-Information/Public-Health-Orders-Response/News-Updates/2021/Mayor-Hancock-Announces-COVID-19-Vaccine-Requirement-for-Employees>; <https://www.bostonherald.com/2021/08/19/baker-issues-vaccine-mandate-for-42000-state-employees/>.

children to attend public school.⁴⁴ Washington, D.C. has already announced a mandate for students ages 12 and older.⁴⁵

III. PHMPT's FOIA Request for the Moderna Vaccine's BLA File

48. In furtherance of PHMPT's mission to disseminate information to the public, and in an effort to ensure that FDA acts consistent with its commitment to transparency,⁴⁶ PHMPT submitted a FOIA request on February 23, 2022, seeking the following documents to be produced on an expedited basis pursuant to 5 U.S.C. § 552(a)(6)(E)(v)(II):

All data and information for the Moderna Vaccine enumerated in 21 C.F.R. § 601.51(e)⁴⁷ with the exception of publicly available reports on the Vaccine Adverse Events Reporting System.⁴⁸

(Exhibit 1.)

49. On March 7, 2022, FDA denied PHMPT's request for expedited processing ("**PHMPT's Denial Letter**" or "**Denial Letters**") and assigned the request FOIA Control # 2022-1614. In PHMPT's Denial Letter, FDA stated, in relevant part:

I have determined that your request for expedited processing does not meet the criteria under the FOIA. You have not demonstrated a compelling need that involves an imminent threat to the life or

⁴⁴<https://www.gov.ca.gov/2021/10/01/california-becomes-first-state-in-nation-to-announce-covid-19-vaccine-requirements-for-schools/>; see also <https://www.latimes.com/california/story/2022-01-24/new-vaccine-legislation-california-schoolchildren-mandate>.

⁴⁵ See <https://abcnews.go.com/US/dc-require-students-12-older-vaccinated-covid-19/story?id=87130087>.

⁴⁶ <https://www.fda.gov/about-fda/transparency>.

⁴⁷ 21 C.F.R. § 601.51(e) provides that after a biological product is licensed, the following information shall be made available for immediate disclosure absent extraordinary circumstances: "(1) All safety and effectiveness data and information. (2) A protocol for a test or study . . . (3) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information . . . (4) A list of all active ingredients and any inactive ingredients . . . (5) An assay method or other analytical method . . . (6) All correspondence and written summaries of oral discussions relating to the biological product file . . . (7) All records showing the manufacturer's testing of a particular lot . . . (8) All records showing the testing of and action on a particular lot by the [FDA]."

⁴⁸ For the avoidance of doubt, this request includes but is not limited to all of the data and information in the biological product file, as defined in 21 C.F.R. § 601.51(a), for the Moderna Vaccine enumerated in 21 C.F.R. § 601.51(e), with the exception of publicly available reports on the Vaccine Adverse Events Reporting System.

physical safety of an individual. Neither have you demonstrated that there exists an urgency to inform the public concerning actual or alleged Federal Government activity. Therefore, I am denying your request for expedited processing.

(Exhibit 2.)

50. On June 1, 2022, PHMPT submitted an appeal challenging FDA's decision to deny PHMPT's requests for Expedited Processing. **(Exhibit 3.)**

51. FDA acknowledged PHMPT's appeal on June 1, 2022, assigned it appeal file 20-0076AA, and declared that the appeal fell under "unusual circumstances" pursuant to 5 U.S.C. § 552(a)(6)(B)(i) and 5 U.S.C. § 552(a)(6)(B)(iii) of the FOIA. **(Exhibit 4.)**

52. Given the "unusual circumstances" claimed by FDA, it was required to make a determination with respect to PHMPT's appeal for expedited processing by July 15, 2022. As of the date of this filing, FDA has not made a determination.

IV. PHMPT's FOIA Request for the 12-15-Year-Old Pfizer Vaccine's BLA File

53. In furtherance of PHMPT's mission to disseminate information to the public, and in an effort to ensure that FDA acts consistent with its commitment to transparency,⁴⁹ PHMPT submitted the following FOIA request to FDA on August 8, 2022 and sought expedited processing pursuant to 5 U.S.C. § 552(a)(6)(E)(v)(II):

All data and information for the 12-15-Year-Old Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e)⁵⁰ with the exception of

⁴⁹ <https://www.fda.gov/about-fda/transparency>.

⁵⁰ 21 C.F.R. § 601.51(e) provides that after a biological product is licensed, the following information shall be made available for immediate disclosure absent extraordinary circumstances: "(1) All safety and effectiveness data and information. (2) A protocol for a test or study (3) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information (4) A list of all active ingredients and any inactive ingredients (5) An assay method or other analytical method (6) All correspondence and written summaries of oral discussions relating to the biological product file (7) All records showing the manufacturer's testing of a particular lot (8) All records showing the testing of and action on a particular lot by the [FDA]."

publicly available reports on the Vaccine Adverse Events Reporting System.⁵¹

This request excludes any data and information responsive to and being produced in FOIA Control # 2021-5683 (previously made on behalf of PHMPT) and is meant to capture all data and information within the biological product file that concerns the authorization and approval of Comirnaty for use in 12-15-year-olds.

(Exhibit 5.)

54. On August 15, 2022, FDA denied PHMPT's request for expedited processing ("PHMPT's Denial Letter" or "Denial Letters"). In PHMPT's Denial Letter, FDA stated, in relevant part:

I have determined that your request for expedited processing does not meet the criteria under the FOIA. You have not demonstrated a compelling need that involves an imminent threat to the life or physical safety of an individual. Neither have you demonstrated that there exists an urgency to inform the public concerning actual or alleged Federal Government activity. Therefore, I am denying your request for expedited processing.

(Exhibit 6.)

V. The de Garays' FOIA Request

55. In furtherance of the de Garays' advocacy for their vaccine-injured daughter, as well as their public advocacy in educating the public of the serious adverse events children may experience after receiving the 12-15-Year-Old Pfizer Vaccine, and in an effort to ensure that FDA acts consistent with its commitment to transparency,⁵² the de Garays submitted the following request to FDA on August 22, 2022 and sought expedited processing pursuant to 5 U.S.C. § 552(a)(6)(E)(v)(II)::

⁵¹ For the avoidance of doubt, this request includes but is not limited to all of the data and information in the biological product file, as defined in 21 C.F.R. § 601.51(a), for the 12-15-Year-Old Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e) with the exception of publicly available reports on the Vaccine Adverse Events Reporting System.

⁵² <https://www.fda.gov/about-fda/transparency>.

All data and information for the 12-15-Year-Old Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e)⁵³ with the exception of publicly available reports on the Vaccine Adverse Events Reporting System.⁵⁴

This request excludes any data and information responsive to and being produced in FOIA Control # 2021-5683 (as that will be publicly available) and is meant to capture all data and information within the biological product file that concerns the authorization and approval of Comirnaty for use in 12-15-year-olds.

(Exhibit 7.)

56. On August 29, 2022, FDA denied the de Garays’ request for expedited processing (“**de Garays’ Denial Letter**” or “**Denial Letters**”) and assigned the request FOIA Control # 2022-6129. In the de Garays’ Denial Letter, FDA stated in relevant part:

I have determined that your request for expedited processing does not meet the criteria under the FOIA. You have not demonstrated a compelling need that involves an imminent threat to the life or physical safety of an individual. Neither have you demonstrated that there exists an urgency to inform the public concerning actual or alleged Federal Government activity. Therefore, I am denying your request for expedited processing.

(Exhibit 8.)

ARGUMENT

57. FOIA provides for “expedited processing of request for records” upon a showing of “compelling need.” 5 U.S.C. § 552(a)(6)(E)(i)(I). As defined by FOIA, a “compelling need”

⁵³ 21 C.F.R. § 601.51(e) provides that after a biological product is licensed, the following information shall be made available for immediate disclosure absent extraordinary circumstances: “(1) All safety and effectiveness data and information. (2) A protocol for a test or study . . . (3) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information . . . (4) A list of all active ingredients and any inactive ingredients . . . (5) An assay method or other analytical method . . . (6) All correspondence and written summaries of oral discussions relating to the biological product file . . . (7) All records showing the manufacturer’s testing of a particular lot . . . (8) All records showing the testing of and action on a particular lot by the [FDA].”

⁵⁴ For the avoidance of doubt, this request includes but is not limited to all of the data and information in the biological product file, as defined in 21 C.F.R. § 601.51(a), for the 12-15-Year-Old Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e) with the exception of publicly available reports on the Vaccine Adverse Events Reporting System.

is justified when the person requesting information is (A) “primarily engaged in disseminating information” and (B) there is an “urgency to inform the public concerning actual or alleged Federal Government activity.” 5 U.S.C. § 552(a)(6)(E)(v)(II).

58. When an agency denies a request for expedited processing, the decision is subject to immediate judicial review. 5 U.S.C. § 522(a)(6)(E)(iii). A requester is not required to pursue an administrative appeal before seeking judicial review of its request for expedited processing of a FOIA request. *Elec. Privacy Info. Ctr. v. Dep’t of Defense*, 355 F. Supp. 2d 98, 100 (D.D.C. 2004).

59. Therefore, as demonstrated above,⁵⁵ Plaintiffs are authorized to bring this action because their requests for expedited processing have been denied by FDA.

60. Furthermore, as explained below, both Plaintiffs can demonstrate a “compelling need” for the expedited processing of their FOIA requests. 5 U.S.C. § 552(a)(6)(E)(i)(I); 5 U.S.C. § 552(a)(6)(E)(v)(II).

I. Plaintiffs Are Primarily Engaged in Disseminating Information

61. In this instance, FDA’s Denial Letters do not challenge the Plaintiffs’ claims that they are primarily engaged in disseminating information.

62. PHMPT is an organization made up of public health professionals, medical professionals, scientists, and journalists. PHMPT exists for the sole purpose of disseminating to the public the data and information in the biological product files for each of the COVID-19 Vaccines. PHMPT intends to make any records produced in response to this FOIA request immediately available to the public through both its website and its individual members’ platforms, as it has with the Comirnaty data. Many of PHMPT’s individual members, including all of its

⁵⁵ See, e.g., *supra* ¶¶ 48-52

members that are journalists, are primarily engaged in disseminating information to the public and do so across various platforms, including through interviews,⁵⁶ articles,⁵⁷ blogs,⁵⁸ essays,⁵⁹ and podcasts.⁶⁰ PHMPT and its members fully intend to analyze and disseminate the data and information underlying the licensure (or FDA “approval”) of the COVID-19 Vaccines, that it hopes to receive from its FOIA requests.

63. The de Garays have become influential public advocates in educating the public on the serious adverse events children may experience after receiving the 12-15-Year-Old Pfizer Vaccine. Their advocacy began shortly after their daughter, M.D., who was a participant in the clinical trials for the 12-15-Year-Old Pfizer Vaccine,⁶¹ suffered the extreme adverse reaction that ultimately necessitated her continued use of a feeding tube and wheelchair.⁶² As part of the de Garays’ public advocacy, they have worked with a number of media organizations including Fox

⁵⁶ See, e.g., <https://www.foxnews.com/transcript/ingraham-angle-on-mask-mandates-bidens-failure-in-his-role> (Harvey Risch).

⁵⁷ See, e.g., <https://www.bmj.com/content/373/bmj.n1244> (Peter Doshi); <https://www.bmj.com/content/371/bmj.m4058> (Peter Doshi); <https://www.bmj.com/content/371/bmj.m4037> (Peter Doshi); <https://www.wsj.com/articles/are-covid-vaccines-riskier-than-advertised-11624381749>; <https://www.wsj.com/articles/university-vaccine-mandates-violate-medical-ethics-11623689220> (Aaron Kheriaty and Gerard V. Bradley); <https://thefederalist.com/2021/07/05/how-college-covid-vaccine-mandates-put-students-in-danger/> (Andrew Bostom, Aaron Kheriaty, Peter A. McCullough, Harvey A. Rish, Michelle Cretella, and Gerard V. Bradley); <https://thefederalist.com/2021/08/18/why-forcing-unvaccinated-students-to-wear-cloth-masks-is-anti-science/> (Andrew Bostom, Gerard Bradley, Aaron Kheriaty, and Harvey Risch); <https://www.bmj.com/content/bmj/374/bmj.n1737.full.pdf> (Serena Tinari and Catherine Riva); <https://www.bmj.com/content/372/bmj.n627> (Serena Tinari); <https://ebm.bmj.com/content/early/2021/08/08/bmjebm-2021-111735> (Sarah Tanveer, Anisa Rowhani-Farid, Kyungwan Hong, Tom Jefferson, Peter Doshi); <https://www.arcdigital.media/p/medical-ethicist-sues-the-university> (Justin Lee).

⁵⁸ See, e.g., <https://blogs.bmj.com/bmj/2021/08/23/does-the-fda-think-these-data-justify-the-first-full-approval-of-a-covid-19-vaccine/> (Peter Doshi); <https://blogs.bmj.com/bmj/2020/11/26/peter-doshi-pfizer-and-modernas-95-effective-vaccines-lets-be-cautious-and-first-see-the-full-data/> (Peter Doshi); see also <https://www.re-check.ch/wordpress/en/covid-certificate/> (Catherine Riva and Serena Tinari).

⁵⁹ See <https://www.andrewbostom.org/2021/06/why-collegiate-covid-19-vaccine-mandates-are-lysenkoist-anti-science/> (Andrew Bostom).

⁶⁰ See, e.g., <https://www.andrewbostom.org/2021/05/dr-andrew-bostom-discusses-the-unfavorable-risk-benefit-ratio-of-covid-19-vaccination-of-very-low-covid-19-risk-12-to-17-year-olds-with-pfizers-emergency-use-authorization-only-mrna-vaccine/> (Andrew Bostom).

⁶¹ See Patrick de Garay’s Declaration (**Exhibit 7 at pages 9-10.**)

⁶² <https://www.foxnews.com/media/ohio-woman-daughter-covid-vaccine-reaction-wheelchair>.

News and the Highwire, as well as advocacy groups, that have and will continue to disseminate their story. These include:

- a. June 28, 2021: Appearance on Senator Ron Johnson's press conference with individuals who suffered adverse reactions to COVID-19 vaccines.⁶³
- b. June 29, 2021: Federalist Article: "Twitter Censors Video of Mother Describing Daughter's COVID-19 Vaccine Side Effects."⁶⁴
- c. July 1, 2021: Coverage of testimony at Senator Ron Johnson press conference by Tucker Carlson Tonight.⁶⁵
- d. July 2, 2021: Appearance on Tucker Carlson Tonight.⁶⁶
- e. November 2, 2021: Appearance on Senator Ron Johnson's Expert Panel on Federal Vaccine Mandates.⁶⁷
- f. December 12, 2021: Australian Senator Gerard Rennick Facebook post on de Garay testimony.⁶⁸
- g. January 12, 2022: Discussion of de Garays by podcast host Joe Rogan on the Joe Rogan Experience.⁶⁹
- h. January 27, 2022: Interview by Epoch Times.⁷⁰

⁶³ <https://youtu.be/lAeVLdMnerQ?t=1885>.

⁶⁴ <https://thefederalist.com/2021/06/29/twitter-censors-video-of-mother-describing-daughters-covid-19-vaccine-side-effects/>.

⁶⁵ <https://www.foxnews.com/transcript/tucker-people-in-charge-create-disaster-after-disaster> at 12:00.

⁶⁶ <https://video.foxnews.com/v/6262045756001#sp=show-clips>.

⁶⁷ <https://rumble.com/vokrf7-sen.-johnson-expert-panel-on-federal-vaccine-mandates.html> at 22:25.

⁶⁸ <https://www.facebook.com/watch/?v=637650331001531>.

⁶⁹ <https://rumble.com/vsgwe2-joe-rogan-on-maddie-de-garay-and-suppression-of-vaccine-adverse-events..html>.

⁷⁰ https://www.theepochtimes.com/the-vaccine-injured-and-their-fight-for-treatment-transparency-trial-participants-stephanie-and-maddie-de-garay-and-brianne-dressen_4241609.html#welcomeuser=1.

- i. April 7, 2022: Interview on Operation Mama Bears.⁷¹
- j. April 10, 2022: Appearance at Defeat the Mandates Rally at Grand Park, Los Angeles, CA.⁷²
- k. May 5, 2022: Interview on Broken Truth.⁷³
- l. June 28, 2022: Interview on Blaze Media's Conservative Review.⁷⁴
- m. August 13, 2022: Appearance on The HighWire, "Rigged: Maddie's Story."⁷⁵

64. Therefore, both Plaintiffs are "primarily engaged in disseminating information to the general public." 5 U.S.C. § 552(a)(6)(E)(v)(II).

II. There Is an Urgency to Inform the Public Concerning Actual or Alleged Federal Government Activity

65. First, the urgency to inform the public concerning the data and information underlying a licensed vaccine is reflected in the Code of Federal Regulations which expressly provides that "[a]fter a license has been issued, the following data and information in the biological product file are *immediately available for public disclosure* unless extraordinary circumstances are shown: (1) All safety and effectiveness data and information" 21 C.F.R. § 601.51(e) (emphasis added). Therefore, FDA's own regulations expressly recognize the importance of having the data and information relied upon to license a vaccine "immediately available for public disclosure." *Id.* FDA's regulation not only supports the need for expedited treatment under FOIA but is also an independent legal basis that requires expedited treatment of this request.

⁷¹ <https://www.youtube.com/watch?v=25kYj80Wn-g>.

⁷² <https://rumble.com/v10yrh1-vaccine-injured-speak-out-at-defeat-the-mandates-los-angeles-ca.html> at 7:00.

⁷³ <https://brokentrueth.com/108-clinical-trials-harm-kids/>.

⁷⁴ <https://www.iheart.com/podcast/263-the-conservative-co-28419175/episode/the-full-story-of-maddie-de-98826546/>.

⁷⁵ <https://thehighwire.com/videos/rigged-maddies-story/>.

66. Moreover, FDA may only license vaccines that have been proven to be “safe and effective,” *see, e.g.*, 21 U.S.C. § 393, and FDA makes this determination based on, *inter alia*, clinical trial reports provided by the sponsor which must be sufficient to demonstrate the product is both “safe” and “effective.”⁷⁶ 21 C.F.R. § 601.2(a). To assure FDA’s commitment to transparency,⁷⁷ and to promote the public’s and the medical and scientific communities’ confidence in the conclusions reached by FDA, it is not surprising that 21 C.F.R. § 601.51(e) requires FDA to immediately disclose all safety and effectiveness data and information after a product is licensed, absent any extraordinary circumstances. This is the same information that would be responsive to the Plaintiffs’ requests.

67. Beyond FDA’s own regulations which admit the urgent need for transparency and disclosure for the requested information, there are two additional reasons that warrant expedited treatment of this request.

68. First, as explained above,⁷⁸ there is an ongoing, national public debate regarding the adequacy of the data and information, and analyses of same, relied upon by FDA to license the COVID-19 Vaccines.

69. Although public health officials, media outlets, journalists, scientists, politicians, public figures, and others with large social or media platforms that have declared that the data and information underlying the licensure of the COVID-19 Vaccines are more than sufficient for licensure, numerous public health officials, media outlets, journalists, scientists, politicians, public

⁷⁶ FDA explains in its guidance materials that the clinical trials relied upon for approval are typically “1 to 4 years” (<https://www.fda.gov/patients/drug-development-process/step-3-clinical-research>) and the duration of clinical trials should “reflect the product and target condition.” <https://www.fda.gov/media/102332/download>; *see also* <https://www.fda.gov/consumers/consumer-updates/it-really-fda-approved>; <https://www.fda.gov/about-fda/what-we-do>.

⁷⁷ <https://www.fda.gov/about-fda/transparency>.

⁷⁸ *See, e.g., supra* ¶¶ 36-45.

figures, and others with large social or media platforms have publicly raised questions regarding the sufficiency of the data and information, the adequacy of the review, and appropriateness of the analyses relied upon to license the COVID-19 Vaccines, including a number of the scientists and journalists that are members of PHMPT.

70. The public debate is unlikely to be settled without full disclosure of the data and information underlying FDA's conclusion that the COVID-19 Vaccines are "safe and effective."

71. Secondly, there is also an urgent need for the public to have immediate access to the data and information underlying the licensure of the COVID-19 Vaccine because, over the objections of many, this product has been, and continues to be mandated to individuals across the country by the federal government, local governments, public and private employers, universities, schools, and various other institutions.⁷⁹

72. While the presence of these mandates continues to fluctuate over the course of the various stages of the COVID-19 pandemic, at the federal level, the Pentagon has continued to mandate COVID-19 vaccines for all military personnel.⁸⁰

73. The urgency regarding the safety and effectiveness information is especially relevant for United States Military. Despite the passage of deadlines for active-duty members to receive the COVID-19 vaccines, tens-of-thousands of active-duty service members refuse to get them.⁸¹

⁷⁹ See, e.g., *supra* ¶¶46-47.

⁸⁰ <https://thehill.com/policy/defense/568996-pentagon-to-mandate-covid-19-vaccine-for-military/>; see also <https://www.nbcnews.com/news/military/deadline-passes-one-10-army-national-guard-soldiers-still-unvaccinated-rcna36269>.

⁸¹ <https://www.forbes.com/sites/teakvetenadze/2021/12/15/military-starts-ejecting-unvaccinated-service-members/?sh=7981d3146ed0>.

74. Most recently, the Army announced roughly 40,000 National Guardsmen and 22,000 reservists will be barred from service for refusing to get vaccinated against COVID-19. This decision effectively cuts off the pay and benefits for more than 60,000 service members and prohibits them from participating in training.⁸²

75. These separations of service members ironically come at a time when the military faces serious recruiting challenges.⁸³ For example, after the first five months of 2022, the Army reached only 23% of its active-duty goal for new recruits, and the Air Force obtained 2,300 fewer recruits in the first fiscal quarter than it did in 2021.⁸⁴ Army Gen. Joseph Martin, Vice Chief of Staff for the Army, has stated that, if these short falls continue, they may have an impact on the military's readiness.⁸⁵

76. With regards to the 12-15-Year-Old Pfizer Vaccine, after its FDA approval, policy makers are reviewing the available information to determine if COVID-19 vaccine requirements are appropriate for students for the 2022-2023 school year, and beyond.⁸⁶

77. Having multiple trusted independent authorities review the safety and effectiveness data sought in these FOIA requests will only assist the public, as well as private institutions, in evaluating vaccine decisions and policies.

78. During a time when COVID-19 vaccine mandates are being implemented over the objection of those who have questions about the data and information supporting the safety and efficacy of the COVID-19 Vaccines, and individuals with these questions are being expelled from

⁸² <https://nypost.com/2022/07/08/army-cuts-pay-from-over-60k-unvaccinated-national-guard-reserves/>.

⁸³ <https://thehill.com/opinion/national-security/3527921-the-military-has-a-serious-recruiting-problem-congress-must-fix-it/>; see also <https://www.military.com/daily-news/2022/07/06/army-cuts-off-more-60k-unvaccinated-guard-and-reserve-soldiers-pay-and-benefits.html>.

⁸⁴ *Id.*

⁸⁵ <https://www.pbs.org/newshour/politics/army-cuts-expected-force-size-amid-unprecedented-shortfall-of-recruits>.

⁸⁶ *See, e.g., supra* ¶¶ 46-47.

employment, school, transportation, restaurants, entertainment facilities, and the military, the public has an urgent and immediate need to have access to this data.

79. Finally, the information Plaintiffs seek concerns actual or alleged federal government activity – namely, whether FDA properly approved the COVID-19 Vaccines based on adequate data and information. Additionally, Plaintiffs’ requests concern FDA’s regulatory obligation to make parts of the COVID-19 Vaccines BLA file “immediately available for public disclosure” once a license has been issued.⁸⁷ Such parts include all safety and effectiveness data and information,⁸⁸ which is precisely the information Plaintiffs’ FOIA requests seek on an expedited basis. (**Exhibit 1, 5 & 8.**)

80. The general public’s interest in the data sought by the Plaintiffs’ requests has already been demonstrated by the public’s engagement with the ongoing release of similar data from PHMPT’s litigation to disclose the BLA file for Pfizer’s COVID-19 vaccine, Comirnaty.⁸⁹ The data produced by FDA has been made public on PHMPT’s website. Despite the fact that only a portion of the data has been released, and hence is not yet ready for proper analysis by the public, there have been approximately three-quarters of a million downloads of the documents and data released to date by members of the public. The website itself has drawn over 2.7 million visitors and 4.5 million views in the last 12 months which makes clear that the public, and especially individuals involved in healthcare, have a sincere interest in viewing the documents considered by the FDA in approving Pfizer’s COVID-19 vaccine and the legal process which led to their release.

81. Therefore, Plaintiffs have demonstrated that they are primarily engaged in disseminating information and that there is an urgency to inform the public concerning actual or

⁸⁷ 21 C.F.R. § 601.51(e).

⁸⁸ *Id.*

⁸⁹ *See, e.g., supra* ¶¶ 27-30.

alleged Federal Government activity and, thus, FDA should provide expedited processing for the requested records because Plaintiffs have a “compelling need”. 5 U.S.C. § 552(a)(6)(E)(i)(I).

REQUESTED RELIEF

WHEREFORE, Plaintiffs pray that this Court:

- a. Provide for expeditious proceedings in this action;
- b. Enter an order directing FDA to produce all responsive documents at the rate of 55,000 pages per month after the FDA completes its production in the related case, *Public Health and Medical Professionals for Transparency v. Food and Drug Administration*, Index No. 4:21-cv-01058-P;
- c. Award Plaintiffs their costs and reasonable attorneys’ fees incurred in this action as provided by 5 U.S.C. § 552(a)(4)(E); and
- d. Grant such other and further relief as the Court may deem just and proper.

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